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# The Country Heart Attack Prevention (CHAP) Project: implementation of an evidence based cardiac rehabilitation model of care for rural and remote patients: design paper



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## TITLE PAGE

**Title: The Country Heart Attack Prevention (CHAP) Project: implementation of an evidence-based cardiac rehabilitation model of care for rural and remote patients: design paper**

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## ABSTRACT (300 WORDS)

### INTRODUCTION

Despite extensive evidence of its benefits and recommendation by guidelines, cardiac rehabilitation (CR) remains highly underutilised with only 30-40% of patients attending a program after hospital discharge. We aim to implement and evaluate the Country Heart Attack Prevention (CHAP) model of care to improve CR attendance and completion for rural and remote participants.

### METHODS AND ANALYSIS

CHAP will apply the Model for Large Scale Knowledge Translation to develop and implement a model of care to CR. Partnering with patients, clinicians and health service managers we will co-develop new approaches and refine/expand existing ones to address known barriers to CR attendance. A patient-centred approach will guide the co-design of telehealth options with patients and provide them with choices for CR modes of delivery. To increase referral rates, CHAP will promote endorsement of CR among clinicians and develop an electronic system that automatizes referrals of in-hospital eligible patients to CR. A business model that enables payment of CR delivered in primary care will enable sustainable access to CR. To promote CR quality improvement, professional development interventions and an accreditation program of CR services and programs will be developed. To evaluate 12-month CR attendance/completion (primary outcome), clinical and cost-effectiveness (secondary outcomes) between patients exposed and not exposed to CHAP, we will have a multi-design approach that encompasses a cohort study, a pre-post study and a comprehensive economic evaluation.

### ETHICS AND DISSEMINATION

This study was approved by the Southern Adelaide Clinical Human Research Ethics Committee Research Committee (HREC/20/SAC/78), which approved a waiver of informed consent. Findings and dissemination to patients and clinicians will be through a public website, online educational sessions, and scientific publications. De-identified data will be available from the corresponding author on reasonable request.

**Trial registration:** Australia New Zealand Clinical Trials Registry (ANZCTR), ACTRN12621000222842, registered 03/03/2021.


**Keywords:** (3-10 words) *Cardiology, Preventive Medicine, Telemedicine*

## STRENGTHS AND LIMITATIONS OF THIS STUDY

- The study will apply the Model for Large Scale Knowledge Translation to partner with patients, health professionals and managers, co-develop and implement a model of care to increase attendance to cardiac rehabilitation in rural and remote areas of South Australia
- Applying a patient-centred care approach, the CHAP model of care will co-design web-based cardiac rehabilitation and allow patients to choose their preferred mode of delivery, evaluate patient-reported outcome and experiences measures (PROMs and PREMs)
- To evaluate the clinical effectiveness of the model of care, a multi-methods approach that includes a cohort study design, pre-post study design will be adopted
- A comprehensive economic analysis to evaluate the cost efficiencies to health services, and the cost-benefit to rural and remote patients and families will be performed.
- At this stage, the CHAP model of care may not suit the needs of Aboriginal and Torres Strait Islander peoples living in rural and remote areas of South Australia, and will warrant further cultural adaption.

## INTRODUCTION

Cardiovascular diseases (CVD) are the number one cause of death globally, taking an estimated 17.9 million lives each year. CVD are a group of disorders of the heart and blood vessels and include coronary heart disease, cerebrovascular disease, rheumatic heart disease and other conditions such as heart failure and arrhythmias.[1] The rate of CVD secondary events globally is estimated to be between 26-50%.[1] CVD kills one Australian every 12 minutes and is a major cause of mortality accounting for 43,249 deaths in 2019.[2]

Of particular concern are those Australians living in rural and remote areas, who have 90% higher rates of CVD-related hospitalisation and 60% higher rates of CVD death than those in metropolitan areas.[3] The further a person lives from a metropolitan centre, the greater their risk of hospitalisation and death from CVD.[4 5 6] In South Australia, a southern, central state of Australia with 1.76 million inhabitants, approximately 23% of the population live in regional areas (i.e., towns, small cities and areas that lie beyond the capital city of Adelaide).[7] Alarmingly, the prevalence of risk factors for heart disease in South Australia is higher than the national average [8] and the age-standardised rate for hospital admissions related to heart disease was the third worst among Australian states in 2017 (120 per 10,000 persons) with some regional areas having mortality rates for coronary heart disease 18% higher than the state average.[5]

### Cardiac Rehabilitation (CR) evidence translation gap

CR is the sum of interventions required to ensure physical, psychological and social recovery for patients after an acute cardiovascular event.[9] Despite high levels of evidence supporting benefit and cost effectiveness of risk factor modification to reduce secondary CVD events through CR,[10] Australian and international statistics, for the past 20 years report that only 20-50% of eligible patients attend.[10 11 12]

Historically, CR has been delivered face-to-face to groups in acute hospitals or community centres.[13] Alternative methods for provision of CR are effective but few have been implemented into practice.[13 14] Therefore, we would argue that the evidence for strategies to modify risk factors through CR is strong but the evidence for the mode of delivery has become outdated. [14 15] Research on the reasons for non-attendance have cited, cost and access issues , limited models of care to accommodate patients who wish to return to work and a lack of person-centredness in service design and delivery.[16] This particularly affects attendance of women, people with disabilities, rural and remote dwellers, and culturally and linguistically diverse populations.[16]

**Preliminary data and background of the Country Heart Attack Prevention (CHAP) Project**

Preliminary data and background leading to the CHAP project have been developed over a decade (2009-2018) through a longstanding partnership among local researchers, clinicians and health service managers. Through this partnership, our team have summarised the evidence around CR, identified local barriers, and implemented and measured performance of a series of initiatives to improve CR referral, attendance and completion.[4 9 12 14 16-20] Limited referrals to CR, lack of patient-centred approaches and individualised choices, lack of sustainable lifelong commitment to CR supported by primary care, and heterogeneous CR quality have been identified as main barriers.[16 20]

*Limited referrals to CR*

A range of factors influence clinicians' view about CR. Our preliminary work showed that clinicians lacking cardiac qualifications may have limited knowledge and awareness of CR and its benefits. Low agreement among clinicians on patients that are more likely to benefit from

CR, clinicians' personal lifestyle and health belief, and the knowledge on the availability and quality of local CR programs also impact on referral to CR.[20] The lack of standard administrative processes of referral and of reliable systems to support clinicians with these processes have also been identified as reasons for limited referrals to CR.[16 20] To address this, the South Australian Department of Health's (SA Health) Integrated Cardiovascular Clinical Network (iCCnet SA), which is a state-wide provider of clinical network support and practice of evidence-based cardiac care and continuous quality improvement servicing regional, rural and remote areas of South Australia, implemented the Country Access to Cardiac Health (CATCH) program.[17 18] This program includes a central referral process that receives CR referrals for patients discharged from public and private hospitals and directs them to a face-to-face or telephone-based CR service depending on patient's preferences and proximity to a CR community centre.[18]

*Lack of patient-centred approaches and individualised choices*

The CATCH program also implemented a telephone-based CR service that is offered to patients living at least 50km away from a CR service.[18] The CATCH telephone program is aligned with findings from a systematic review conducted by members of our team that showed that individualised telehealth or home-based CR programs were effective alternative models that are comparable to the traditional hospital and community-based programs in terms of reducing CVD risk factors.[14 18] These telehealth options are particularly important to Australians living in rural and remote areas where distances and lower availability of services amplify limitations to CR access.[4 16 19 6] In an analysis conducted in 2015, regional and rural locations receiving the telephone-based CR program showed an increase in referral rates (97.3%), a reduction in all-cause readmissions (3.4% vs 1.8%, p<0.001), and reduced length

of stay for those patients readmitted (3.5 vs 2.7 days, p=0.001) after the program implementation.[18]

*Lack of sustainable lifelong commitment to CR supported by primary care*

Access to a cardiologist is a known enabler of CR uptake.[21] To address the barrier of the shortage of specialists in rural and remote areas throughout Australia,[22] iCCnet has developed a model of care (GP Hybrid network) that enables CR delivery through a strong collaboration among general practitioners (GPs), practice nurses working in rural and remote areas in South Australia and CR nurses working in the CATCH telephone-based service.[23] This service has been evaluated and shown high attendance and completion rates, and enhanced clinical outcomes for patients within 12 months, such as improved lipids and diabetes control. [23] All these measures of performance of the GP Hybrid network were enabled by the establishment of the CATCH database by iCCnet. This CR dataset with standardised electronic data collection serves to audit and feedback purposes to all public face-to-face services and the telephone-based service in the state of South Australia.[17 24]

*Heterogeneous CR quality*

Quality improvement of CR programs is associated with higher rates of attendance and completion.[24] The Australian Cardiovascular Health and Rehabilitation Association (ACRA) recommends five core components for quality delivery and outcomes of CR services - access to services, assessment and monitoring, recovery and longer-term maintenance, lifestyle or behavioural changes, medication adherence, evaluation and quality improvement.[9] National Quality indicators for CR were established by ACRA and the National Heart Foundation of Australia in 2019.[9] However, currently, there is no standardisation of the CR services and programs with only a few meeting minimum duration standards.[25] Therefore, there is large

variation across services in terms of the content, measures, the number of sessions and length of the CR program.

*Aims and Objectives*

The CHAP project aims to develop and implement evidence-based approaches to address modifiable barriers to accessing and successfully completing CR in rural and remote areas of South Australia.

We hypothesise ($H_1$) that compared with patients not exposed to the CHAP model of care (i.e., receiving standard care) patients exposed to CHAP will have higher rates of attendance and completion of CR; higher rates of risk factor modification; higher rates of adherence to evidence-based pharmacotherapy; experience lower rates of morbidity and mortality at 30 days and 12 months and that the model will demonstrate cost effectiveness for both services and patients.

Specific objectives of the CHAP project are to:

1) Adopt a patient-centred approach by co-designing the CHAP model of care with patients family and clinicians and evaluate the impact on CR attendance and completion

2) Evaluate the clinical effectiveness of the CHAP model and

3) Evaluate the cost-effectiveness of the CHAP model

## METHODS AND ANALYSIS

### Study Design

The CHAP project will use a translation methodology (Model for Large Scale Knowledge Translation[26]) to implement a model of care into practice. The model will be assessed through a multi-method approach which includes a pre-post and cohort study designs, and a comprehensive economic evaluation.

*The Model for Large Scale Knowledge Translation*

The Model for Large Scale Knowledge Translation[26] is a generalisable translation model that intends to facilitate implementation of evidence into practice. It is particularly useful for large scale collaborative projects involving researchers and clinical staff. The first three of the four stages of the Model for Large Scale Knowledge Translation (1. Summarise the evidence; 2. Identify local barriers, and 3. Measure performance) have been completed in the decade (2009-2018) of preliminary work by researchers in our team and included 1) systematic review on the effectivenesss of alternative modes of delivery of CR;[14] 2) idenification of local barriers to CR attendance;[16] 3) the establishment of a central referral system (CATCH central referral system) and telephone-based program (CATCH telephone program);[17] [18] and 4) clinical database (CATCH database).[17]

The fourth stage of the model is the final and most complex one – *Ensure all patients receive the intervention*. The model uses a "four Es" approach to improve reliability: engage, educate, execute, and evaluate [26] (Figure 1). This is the stage that will be developed in the CHAP project. The CHAP model of care must fit each hospital or health networks current system, including local culture and resources.

To complete this stage, the team will work closely with health networks and CR services addressing barriers to implementing the CHAP model of care in rural and remote areas of the state (Figure 2).

The evaluation of the CHAP model of care will comprise both clinical (Objective 2) and cost-effectiveness (Objective 3) assessments, and will involve a multi-method approach:

I. A prospective cohort study comparing attendance and clinical outcomes of patients exposed and non-exposed to CHAP - the cohort of patients eligible to CR will be followed-up for 12 months from CHAP implementation and outcomes will be

compared between those exposed to the CHAP model and those not exposed to the model of care. The exposed and non-exposed groups will be age, sex and diagnostic-related groups (DRG) matched controls in a 1:3 ratio;[27]

II. A pre-post study design comparing outcomes before (01/01/2016 to 30/04/2021) and after CHAP implementation (01/05/2021 to 30/04/2023). A comprehensive economic analysis will be performed to evaluate the cost efficiencies to health services, and the cost-benefit to rural and remote patients and families.

**Setting**

The CHAP model of care will be implemented within the six local health networks in regional, rural and remote South Australia through iCCnet.[17] The iCCNet is part of the Rural Support Service (RSS) which is a business unit within the South Australian Health Service that provides flexible, responsive and innovative services to support the six regional local health networks. Regional health services are delivered to a population of 497, 003 people with the following age-group distribution: 0 to 4 years - 5.82%, 5 to 18 years -17.52%, 19 to 64 years - 56.68%, and 65 years and over - 19.98%. There are 23 CR services and the CATCH telephone service. [28]

**Participants**

Eligible participants will be defined according to current international guideline criteria [29] by DRGs based on the International Classifications of Diseases-10 (ICD-10) codes and the current guidelines for those who are eligible for referral to CR these include: acute myocardial infarction (I21, I21.0, I21.1, I21.2, I21.3, I21.4, I21.9), hypertensive heart disease (I11.0, I11.9, I13, I13.0, I13.2, I13.9), ischemic heart disease (I20-I25), arrhythmias (I48, I48.0, I48.1, I48.2, I48.3, I48.4, I48.9, I49.9), and/or heart failure (I50, I50.0, I50.1, I50.9).[30] Eligibility will also be defined based on DRG procedure codes for coronary artery surgery, percutaneous coronary intervention, and ventricular assist device.[31]

All adult (≥18 years) South Australians, including Aboriginal and Torres Strait Islander peoples, discharged from hospital with a diagnosis that meets the eligibility criteria to CR and living within the six local health networks in regional, rural and remote areas will be exposed to the CHAP model of care. The comparison group (non-exposed to CHAP) will be comprised by age, sex and DRG matched controls not living in these regional, rural and remote areas.

We acknowledge we are implementing standard guidelines that may not suit Aboriginal and Torres Strait Islander peoples. A future project to culturally adapt the CHAP model of care using appropriate Aboriginal and Torres Strait Islander translation methodology is warranted.

**Exposure- CHAP model of care**

To co-design and refine the CHAP model of care (Objective 1), we will address four different barriers to CR attendance and completion previously identified (Figure 2)

*1) Limited number of referrals*

We will address the limited number of referrals by promoting CR endorsement among clinicians and providing them with an electronic system that facilitates referrals.

To increase CR endorsement, we will co-design education resources with clinicians including evidence-based pharmacotherapy resources, and a variety of paper-based, videos and web-based education resources. This will ensure that health professionals' and CR patients' needs are addressed regardless of technology literacy levels.[32]

We will expand the capabilities of referral introduced by the CATCH central referral system by developing an automatic electronic referral system that will streamline in-hospital referrals. A central portal for patient discharge reports will provide contact information on patients that have been discharged with applicable codes. Currently, these reports are run from several different databases and have the potential to miss patients living in rural and remote areas. We

will first have automatic reports generated from information taken from the health department (SAH DataMart™). This will all run on the back end of the Integrated Point of Care Clinical System (iPOCCS™)[33] in which an excel document is generated daily, reporting on the previous 24h of discharged patients. A Uniform Resource Locator (URL) will be sent to designated users allowing them log on to iPOCCS and download the file.

*2) Lack of patient-centred approaches and individualised choices*

Face-to-face and telephone services are well established as modes of CR delivery in rural South Australian regions.[18] Despite variability in duration and content, these CR programs are generally based on the National Heart Foundation of Australia [29] and ACRA guidelines [9] being comprised of 10 modules (Initial Assessment and Goal Setting, Heart Education and Self-management, Exercise Training and Physical Activity, Healthy Eating and Weight management, Tobacco Cessation and Alcohol Reduction, Medication Education and Review, Managing Medical Risk Factors, Psychosocial Wellbeing, Activities of Daily Living, Reassessment and Completion) which are delivered over 6 to 12 weeks depending on patient's needs and decisions from services.

To expand choices of CR modes of delivery, CHAP will co-design with patients a web-based program that will be accessed through a personal log-in. The content of the portal will be based on the 10 National Heart Foundation of Australia modules.[9 29] Individualised programs will be tailored according to patients' needs. The anticipated duration of each web module completion is 30 minutes per week. Those in the web-delivery mode will be required to read short texts, watch short videos (about 5 per module), set personal goals, self-report their dietary, physical activity, smoking and alcohol ingestion habits weekly through responding online questionnaires on the website. The web portal will have a function to collect physical activity data from wearables and smartphone apps patients may use. Patients will be able to interact with a CR nurse through a message system embedded in the web portal. They will be asked to

complete four Heart Health Risk Factor Assessments (baseline, 8-12 weeks after starting CR, 6 and 12-months after completing CR). These assessments will have an expected duration of 20 minutes and will be comprised of clinical and PROMS assessment using validated questionnaires that assess lifestyle habits, exercise capacity, quality of life, mental health (Table 1). Six and 12-month follow-up will be performed by the patient's primary carer physician.

**Table 1: Primary and Secondary outcomes, measurements and sources of data**

| **Primary outcomes** | **Measures/ Instruments** |
|---|---|
| Attendance/ Completion | Number of patients attended and completed CR among eligible ones/year |
| **Secondary Outcomes** | |
| CR Referral rates | Number of patients referred to CR/eligible to CR/year |
| 30-day and 12-month hospital CVD-related hospital re-admission | NA |
| 30-day and 12-month CVD-related mortality | NA |
| ***Cardiovascular risk factor modification*** | |
| Smoking | Self-reported number of cigarettes |
| Alcohol intake | Self-reported grams of alcohol consumed/week |
| Body mass index | Self-reported weight and height |
| Nutrition | CSIRO Healthy Diet Score[34] |
| Diabetes control | Hb A1C |
| Exercise, physical activity and functional capacity | 6-minute walk test[35]<br>International Physical Activity Questionnaire-Short Form[36]<br>Specific Activity Questionnaire[37] |
| Medication adherence | Adherence in Chronic Diseases Scale[38] |
| ***Patient-reported outcome measures (PROMs) and patient-reported experience measures (PREMs)*** | |
| Anxiety | Cardiac anxiety questionnaire [39] |
| Depression | PHQ-2, PHQ-9 [40] |
| Quality of life | EQ-5D-5L[41] |

| | |
|---|---|
| | Kansas City Cardiomyopathy Questionnaire-12[42] (for patients with heart failure) |
| Health literacy | Brief Health Literacy Screening tool [43] |
| Patient satisfaction | Self-reported satisfaction |

* NA Not Applicable; PHQ-2 and PHQ-9: the 2- and 9-question Patient Health Questionnaires, respectively; EQ-5D-5L: European Quality of Life- 5 Dimensions – 5 Levels

*Patients and public involvement*

The CHAP model of care is underpinned by a patient-centred approach. Patient-centred care or person-centred care is based on principles that those receiving healthcare must be treated with dignity and respect and be involved in all decisions about their health.[44] This approach is applied in this study through involvement of patients in the co-design of the CR web program and development of a model that allows patients to choose among different CR modes of delivery (face-to-face, telephone or web-based, or combinations of these modes- Figure 2).[44] [45] We will particularly promote the participation of older CR patients and people from cultural and linguistically diverse backgrounds to ensure that groups at increased risk of low technology and health literacy are involved in the co-designing of the web-based CR program. We anticipate this will increase patient adherence and engagement with the web-based CR program.[45]

Updating the modalities of telehealth that are currently available will allow for greater flexibility of CR delivery which can improve access for patients in need. Importantly, this also provides an appropriate response to the COVID-19 pandemic when traditional CR service delivery is disrupted.[46] [47]

*3) Lack of sustainable lifelong commitment to CR supported by primary care*

CHAP project will build upon the GP Hybrid Model of CR delivery by creating a business model which allows primary care to support CR delivery and assessment of CR results (risk factor change) of patients undertaking telephone and web-based CR. The model will comprise

a 'Heart Health Risk Factor' pre-assessment at the beginning of the program (i.e. 1-2 weeks post-discharge) which will last 75 minutes (60 minutes with a Practice Nurse and 15 minutes with the GP). Re-assessments will occur at 8-12 weeks after the beginning of the program, and 6 months and 12 months post-completion of the CR program. These will comprise 45 to 60 minutes consultations with the practice nurse, and 15-minute consultations with the GP. This has potential to enable long term support for heart health from GPs.

*4) Heterogeneous CR quality*

The CHAP project will seek adherence to the quality indicators through multiple online and offline professional development programs targeting the practitioners, development of an accreditation program and refinement of data collection tools on the national CR quality indicators. In particular, the project will try to integrate objective patient-generated physical activity tracking data to the CATCH CR database to enable objective monitoring of physical activity during CR and personalised feedback.

## Outcomes

*Primary outcome* – CR attendance rate defined as the number of patients commencing CR among those eligible to CR.

*Secondary outcomes* - will compare risk factor modification, clinical outcomes, PROMS and PREMS of the CHAP and non-CHAP groups**.** Measurements and data sources for the secondary outcomes are presented in Table 1.

## Data Sources

The CATCH CR database collects data uniformly across metropolitan, rural and remote areas using a standardised electronic entry process, including electronic data capture, of patients moving through public CR services from rural and remote to a metropolitan hospital or vice

versa.[18] This database will be linked to the Integrated South Australian Integrated Activity Collection (ISAAC), which is the SA Health administrative database, enabling follow-up and assessment of hospital re-admissions and mortality.[48]

**Bias**

To avoid information bias (i.e., systematic differences in the completeness or the accuracy of data leading to differential misclassification of individuals regarding exposures or outcomes) we are up-skilling clinicians to input data onto the CR databases as part of continuous quality improvement processes. The goal is to fill the gap of scarcity of data on CR data in Australia [49] and achieve universal, uniform data entry in South Australian CR programs.

**Sample size**

The average state-wide attendance of CR from 2013-2015 was 28.3% (pre-CHAP estimate)[10]. Based upon a 4% improvement in attendance (i.e., to 32.3%) as reported by the British Association for Cardiovascular Prevention and Rehabilitation audit,[50] a total sample size of 1223 (CHAP) and 3669 (usual care, 1:3 matching) will produce a two-sided 95% confidence interval for the difference in population proportions with a width that is equal to 0.06. Allowing for a 20% dropout, we will need to observe 1529 patients (765 per year) in the group exposed to CHAP that will be matched to 4587 patients in the group non-exposed to CHAP (usual care) from the CATCH database. From 2015-2019, approximately 2000 patients were entered into the CATCH CR database per year making this study highly feasible.

**Data analysis**

*To evaluate the effectiveness of CHAP (Objective 2)*

Unpaired *t*-tests, $\chi$ tests and Mann–Whitney *U* tests for non-normal data will be used for comparisons for the pre-post analysis of the CHAP model components. Statistical significance

will be inferred if 2-tailed tests estimated $P<0.05$. Rates of referral, attendance, and completion of CR per year; modification of risk factors; adherence to evidence-based pharmacotherapy morbidity and mortality at 30 days and 12 months will be compared between CHAP and non-CHAP attendees and presented as Odds Ratios and 95% Confidence Intervals. Matching will be conducted by grouping all cases and controls into relevant groupings of Age, Sex and DRG and analysed using the Mantel-Haenszel methods.[51]

Cox regression models adjusted for clinical and social factors (age, sex, the Index of Relative Socio-Economic Advantage and Disadvantage (IRSAD) from the Australian Bureau of Statistics' Socio-Economic Indexes for Areas-SEIFA score,[52] accessibility and Remoteness Index of Australia (ARIA+),[53] primary cardiac diagnosis, Charlson Index,[54] in-hospital length of stay, prior heart failure, coronary disease, atrial fibrillation, revascularisation, malignancy) will be performed to understand the association between exposure to the CHAP model and attendance. For clinical outcomes (30-day and 12-month hospital CVD-related hospital re-admission, 30-day and 12-month CVD-related mortality), the model will also be adjusted for CR attendance.

*To evaluate the cost-effectiveness of CHAP (Objective 3)*

The economic evaluation of the CHAP model including the business model (explore the item numbers that can be utilised to cover GP based CR and items that can be used to employ and train practice nurses to assist with assessment, monitoring, collection of outcomes data and triage to maximise GP consultation time) that involves primary care in CR delivery will comprise: i) the cost efficiencies to health services, and ii) cost-benefit to rural and remote patients and families.

i. *The cost efficiencies to the health services*

All CVD hospitalisations during the follow-up period will be included and assigned a cost, based on the diagnosis-related group category reference and length of stay. Costs of providing CR will be taken from a health system perspective and calculated over 1 year; this includes staffing, consumables, overheads, and capital expenses. Quality-of-life measures will be estimated at baseline, 6 and 12 months after CR completion, using the standard EQ-5D-5L.[41] The utility is defined by the Department of Health and Ageing as a numerical value assigned by an individual to a preference for, or desirability of, a specific level of health status or a specific health outcome. Data on utilities and survival can be combined to calculate Quality-Adjusted Life-Year (QALY) by exposed and non-exposed groups using the Quality-Adjusted Survival Analysis (QASA) method.[55-57] Incremental cost per QALY saved will be calculated as an incremental (rehabilitation v usual care) cost per patient divided by the incremental QALY per patient.[58]

*ii. Cost-benefit to rural and remote patients and families*

Using an economic survey developed by the Western Australian Department of Health[59] we will quantify the economic impact of the CHAP model based on information at baseline including patient demographics such as household structure, employment status and the distances travelled to access services; the nature of the consultation, waiting time, whether the patient required time off work (and if so, how much), and the mode of transport used to travel to the hospital. The survey will include accompanying persons, and if the person required any time off work to do so. Finally, the survey will explore the patient's treatment options; for example, did they consider having an appointment in the city essential to their care? This data will be modelled to compare two scenarios for face-to-face CR; 1) if the patient travelled to the city to attend CR, or 2) if the patient travelled to the nearest rural CR program if this is within 60 minutes' drive (approximately 100 km). All results will be presented unadjusted for multiple comparisons and all analyses will be done on an

intention-to-treat basis. 95% confidence intervals for the difference in QALYs will be calculated with bootstrapping.[56]

**Time Frame of the Project**

This will be a three-year project conducted over four calendar years July 1st, 2019-June 30th, 2022. Due to the impact of the COVID pandemic on the project implementation, the project will now be complete by 30th June 2023. Year 1 will include project staff employment and training, development of resources, education materials, study protocols, additional datasets, and Ethics approval. Recruitment and follow-up will be conducted over years 1-3, analysis and reporting in the last 6 months of Project Year 4.

## ETHICS AND DISSEMINATION

**Ethics approval and consent to participate**

This study was approved by the Southern Adelaide Clinical Human Research Ethics Committee Research Committee on 28th, April 2020 (HREC/20/SAC/78). All consecutive patients who are eligible for CR according to the recommended DRG codes and referred for CR will have consent waiver to have their data used for this research.

**Dissemination**

Findings will be disseminated to patients and health professionals using various means and media. A public website (https://chapproject.com.au), online educational sessions with patients and health professionals working in CR, monthly newsletters sent to participants via email, social media (Twitter @CHAPproject, LinkedIn CHAP Project and Facebook), and scientific publications and conference presentations.

De-identified data will be available upon reasonable request.

**Authors contributions:** The study was conceived and designed by RC, SN, AB, DC, JB, AM, CM, VV, JH, PT, BK, CZ, IP, RT, RT, and WK. The first draft of the paper was written by AB with significant input from RC before receiving input from remaining authors; CA, KG, KN, HD, SC, MAPP, IL, VP, MR, KW, HM, AK, LG, and CG. All authors read and approved the final manuscript.

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**Competing interests:** The authors do not have competing interests.

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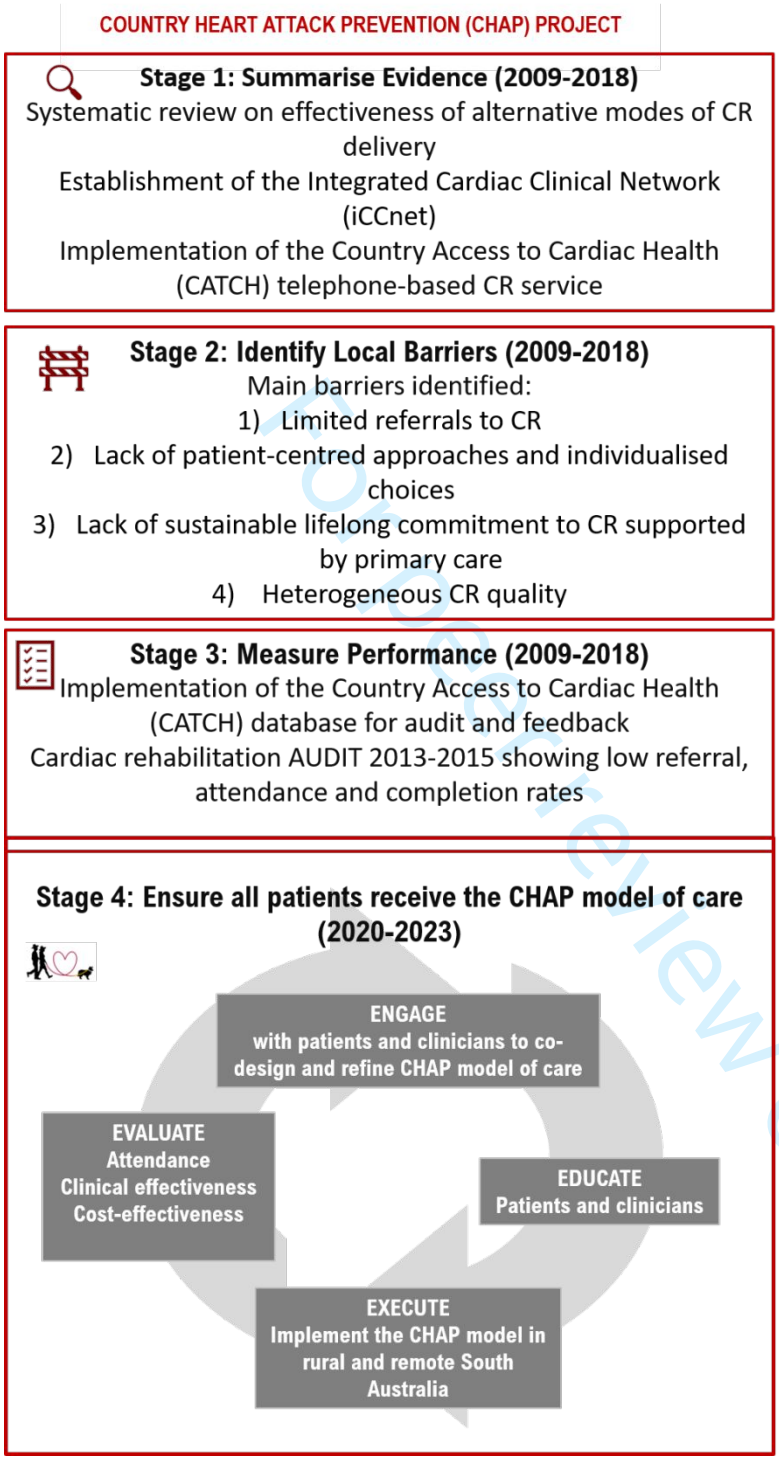
## Legend of Figures and Tables

### Figures

Figure 1: Using the Model for Large Scale Knowledge Translation to develop CHAP

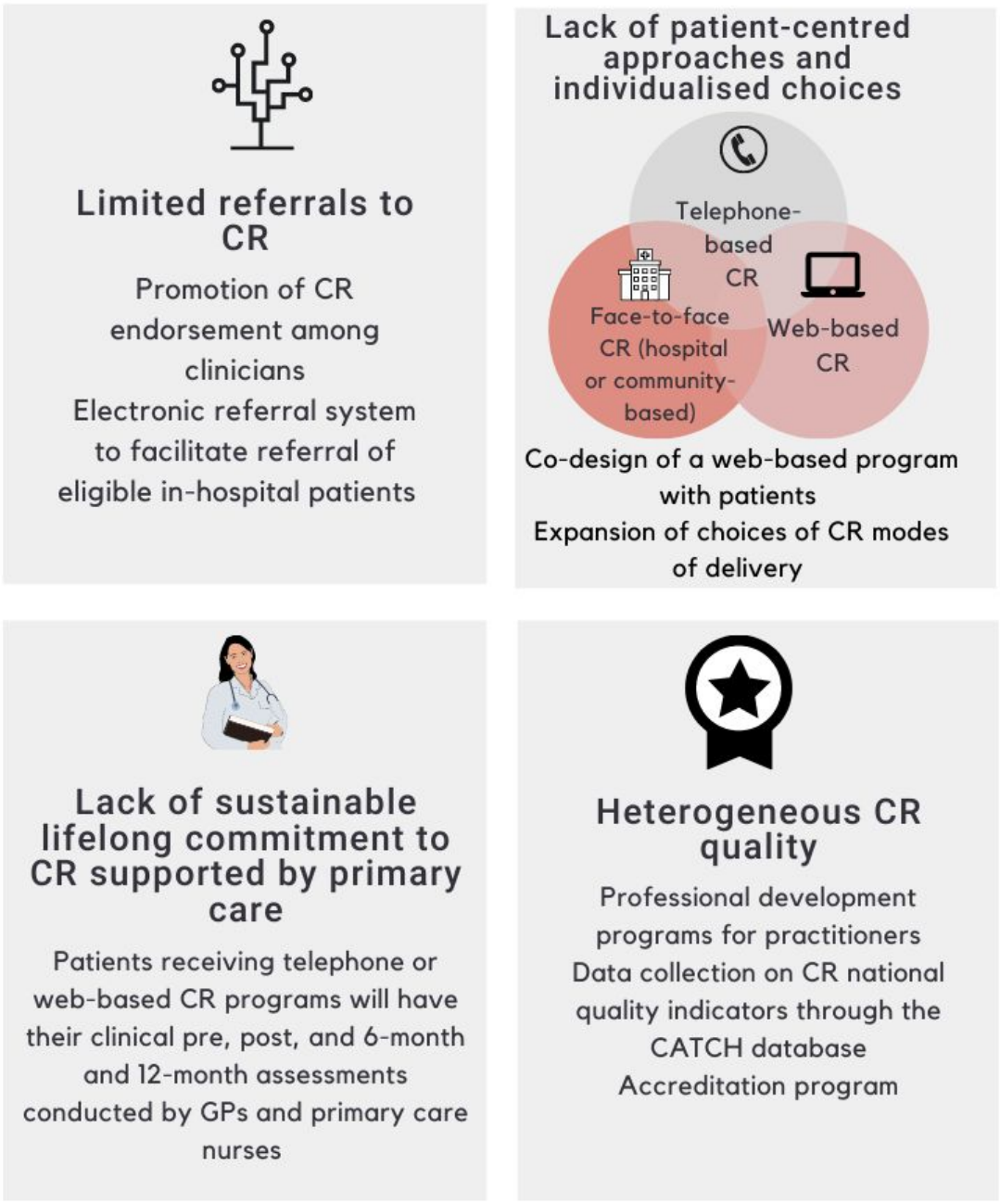
Figure 2: Addressing the barriers through the CHAP model of care (Exposure) according to the 4th Stage of the Model for Large Scale Knowledge Translation ('Engage, Educate, Execute, Evaluate')

**Figure 1: Using the Model for Large Scale Knowledge Translation to develop CHAP**




*(Pronovost PJ, Berenholtz SM, Needham DM. Translating evidence into practice: a model for large scale knowledge translation. BMJ. 2008;337:a1714.)*

**Figure 2: Addressing the barriers through the CHAP model of care (Exposure) according to the 4th Stage of the Model for Large Scale Knowledge Translation ('Engage, Educate, Execute, Evaluate')**



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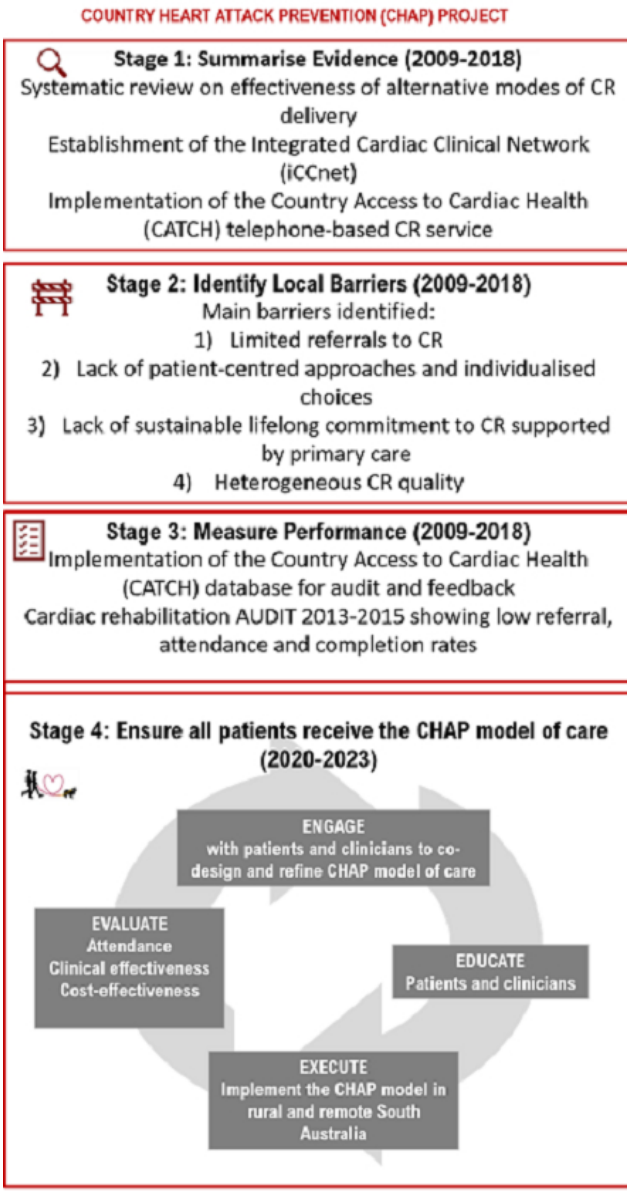


Using the Model for Large Scale Knowledge Translation to develop CHAP

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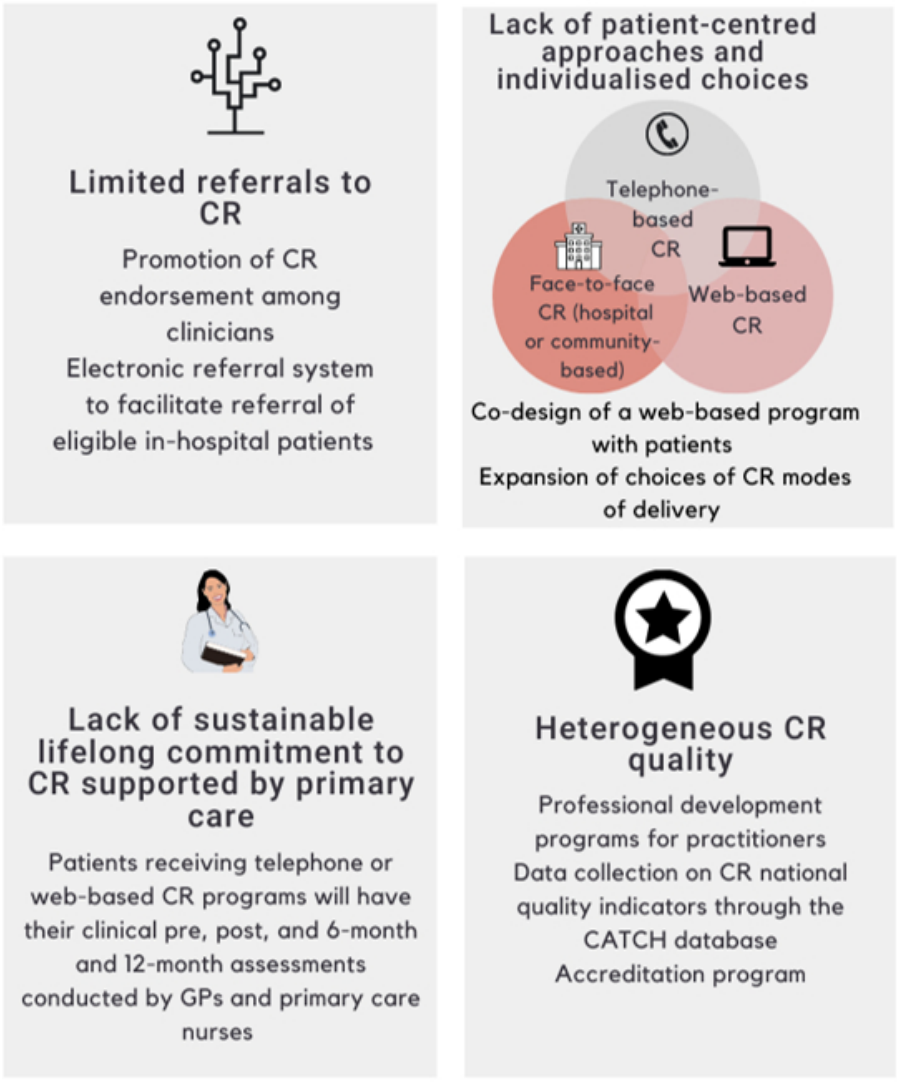


Addressing the barriers through the CHAP model of care (Exposure) according to the 4th Stage of the Model for Large Scale Knowledge Translation ('Engage, Educate, Execute, Evaluate')

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STROBE CHECKLIST

STROBE Statement—Checklist of items that should be included in reports of ***cohort studies***

| | Item No | Recommendation | Page No |
|---|---|---|---|
| **Title and abstract** | 1 | (*a*) Indicate the study's design with a commonly used term in the title or the abstract<br><br>(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found | 1<br><br>4 |
| **Introduction** | | | |
| Background/rationale | 2 | Explain the scientific background and rationale for the investigation being reported | 8-10 |
| Objectives | 3 | State specific objectives, including any prespecified hypotheses | 11 |
| **Methods** | | | |
| Study design | 4 | Present key elements of study design early in the paper | 12 |
| Setting | 5 | Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection | 13 |
| Participants | 6 | (*a*) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up<br><br>(*b*) For matched studies, give matching criteria and number of exposed and unexposed | 14 |
| Variables | 7 | Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable | 14-18 |
| Data sources/ measurement | 8* | For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group | 18 |
| Bias | 9 | Describe any efforts to address potential sources of bias | 19 |
| Study size | 10 | Explain how the study size was arrived at | 19 |

| | | | | |
|---|---|---|---|---|
| | Quantitative variables | 11 | Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why | 20-21<br>Table 1 |
| | Statistical methods | 12 | (*a*) Describe all statistical methods, including those used to control for confounding<br>(*b*) Describe any methods used to examine subgroups and interactions<br>(*c*) Explain how missing data were addressed<br>(*d*) If applicable, explain how loss to follow-up was addressed<br>(*e*) Describe any sensitivity analyses | 20-21 |
| **Results -Not applicable** | | | | |
| Participants | | 13* | (a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed | |
| | | | (b) Give reasons for non-participation at each stage | |
| | | | (c) Consider use of a flow diagram | |
| Descriptive data | | 14* | (a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders | |
| | | | (b) Indicate number of participants with missing data for each variable of interest | |
| | | | (c) *Cohort study*—Summarise follow-up time (eg, average and total amount) | |
| Outcome data | | 15* | *Cohort study*—Report numbers of outcome events or summary measures over time | |
| | | | *Case-control study*—Report numbers in each exposure category, or summary measures of exposure | |
| | | | *Cross-sectional study*—Report numbers of outcome events or summary measures | |
| Main results | | 16 | (*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included | |
| | | | (*b*) Report category boundaries when continuous variables were categorized | |
| | | | (*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period | |

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|---|---|---|
| Other analyses | 17 | Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses |
| **Discussion** | **Not applicable** | |
| Key results | 18 | Summarise key results with reference to study objectives |
| Limitations | 19 | Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias |
| Interpretation | 20 | Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence |
| Generalisability | 21 | Discuss the generalisability (external validity) of the study results |
| **Other information** | | |
| Funding | 22 | Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based |

BMJ Open

# Implementation and prospective evaluation of the Country Heart Attack Prevention model of care to improve attendance and completion of cardiac rehabilitation for patients with cardiovascular diseases living in rural Australia: a study protocol



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|---|---|
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| Secondary Subject Heading: | Health services research |
| Keywords: | PREVENTIVE MEDICINE, CARDIOLOGY, Telemedicine < BIOTECHNOLOGY & BIOINFORMATICS |
| | |

## TITLE PAGE

**Title: Implementation and prospective evaluation of the Country Heart Attack Prevention model of care to improve attendance and completion of cardiac rehabilitation for patients with cardiovascular diseases living in rural Australia: a study protocol**

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## ABSTRACT (300 WORDS)

### INTRODUCTION

Despite extensive evidence of its benefits and recommendation by guidelines, cardiac rehabilitation (CR) remains highly underutilised with only 30-40% of eligible patients participating. We aim to implement and evaluate the Country Heart Attack Prevention (CHAP) model of care to improve CR attendance and completion for rural and remote participants.

### METHODS AND ANALYSIS

CHAP will apply the Model for Large Scale Knowledge Translation to develop and implement a model of care to CR in rural Australia. Partnering with patients, clinicians and health service managers, we will co-develop new approaches and refine/expand existing ones to address known barriers to CR attendance. CHAP will co-design a web-based CR program with patients expanding their choices to CR attendance. To increase referral rates, CHAP will promote endorsement of CR among clinicians and develop an electronic system that automatizes referrals of in-hospital eligible patients to CR. A business model that includes reimbursement of CR delivered in primary care by Medicare will enable sustainable access to CR. To promote CR quality improvement, professional development interventions and an accreditation program of CR services and programs will be developed. To evaluate 12-month CR attendance/completion (primary outcome), clinical and cost-effectiveness (secondary outcomes) between patients exposed (n=1223) and not exposed (n=3669) to CHAP, we will apply a multi-design approach that encompasses a prospective cohort study, a pre-post study and a comprehensive economic evaluation.

### ETHICS AND DISSEMINATION

This study was approved by the Southern Adelaide Clinical Human Research Ethics Committee Research Committee (HREC/20/SAC/78), which approved a waiver of informed consent. Findings and dissemination to patients and clinicians will be through a public website, online educational sessions, and scientific publications. De-identified data will be available from the corresponding author on reasonable request.

**Trial registration:** Australia New Zealand Clinical Trials Registry (ANZCTR), ACTRN12621000222842, registered 03/03/2021.


**Keywords:** (3-10 words) *Cardiology, Preventive Medicine, Telemedicine*

## STRENGTHS AND LIMITATIONS OF THIS STUDY

- The study will apply the Model for Large Scale Knowledge Translation to implement evidence-based cardiac rehabilitation into practice.
- Co-design of telehealth-based cardiac rehabilitation with patients and evaluation of patient-reported outcomes and experiences demonstrate the patient-centred approach of CHAP.
- Data linkage between clinical and administrative databases will allow an accurate evaluation of the model's clinical effectiveness.
- Analysis of the cost efficiencies to health services, and the cost-benefit to rural patients and families will be performed.
- The CHAP model of care is not culturally tailored to the needs of Aboriginal and Torres Strait Islander peoples living in rural South Australia.

## INTRODUCTION

Cardiovascular diseases (CVD) are the number one cause of death globally, taking an estimated 17.9 million lives each year. CVD are a group of disorders of the heart and blood vessels and include coronary heart disease, cerebrovascular disease, rheumatic heart disease and other conditions such as heart failure and arrhythmias.[1] The rate of CVD secondary events globally is estimated to be between 26-50%.[1] CVD kills one Australian every 12 minutes and is a major cause of mortality accounting for 43,249 deaths in 2019.[2]

Of particular concern are those Australians living in rural and remote areas, who have 90% higher rates of CVD-related hospitalisation and 60% higher rates of CVD death than those in metropolitan areas.[3] The further a person lives from a metropolitan centre, the greater their risk of hospitalisation and death from CVD.[4 5 6] In South Australia, a southern, central state of Australia with 1.76 million inhabitants, approximately 23% of the population live in regional areas (i.e., towns, small cities and areas that lie beyond the capital city of Adelaide).[7] Alarmingly, the prevalence of risk factors for heart disease in South Australia is higher than the national average [8] and the age-standardised rate for hospital admissions related to heart disease was the third worst among Australian states in 2017 (120 per 10,000 persons) with some regional areas having mortality rates for coronary heart disease 18% higher than the state average.[5]

### Cardiac Rehabilitation (CR) evidence translation gap

CR is the sum of interventions required to ensure physical, psychological and social recovery for patients after an acute cardiovascular event.[9] Despite high levels of evidence supporting benefit and cost effectiveness of risk factor modification to reduce secondary CVD events through CR,[10] Australian and international statistics, for the past 20 years report that only 20-50% of eligible patients participate.[10 11 12]

Historically, CR has been delivered face-to-face to groups in acute hospitals or community centres.[13] Alternative methods for provision of CR are effective but few have been implemented into practice.[13 14 15] Therefore, we would argue that the evidence for strategies to modify risk factors through CR is strong but the evidence for the mode of delivery has become outdated. [14 16] Research on the reasons for non-attendance have cited, cost and access issues , limited models of care to accommodate patients who wish to return to work and a lack of person-centredness in service design and delivery.[17] This particularly affects attendance of women, people with disabilities, rural and remote dwellers, and culturally and linguistically diverse populations.[17] Moreover, the Covid-19 public health emergency has amplified the barriers on accessing centre-based CR[15].

**Preliminary data and background of the Country Heart Attack Prevention (CHAP) Project**

Preliminary data and background leading to the CHAP project have been developed over a decade (2009-2018) through a longstanding partnership among local researchers, clinicians and health service managers. Through this partnership, our team have summarised the evidence around CR, identified local barriers, and implemented and measured performance of a series of initiatives to improve CR referral, attendance and completion.[4 9 12 14 17-21] Limited referrals to CR, lack of patient-centred approaches and individualised choices, lack of sustainable lifelong commitment to CR supported by primary care, and heterogeneous CR quality have been identified as main barriers.[17 21]

*Limited referrals to CR*

A range of factors influence clinicians' view about CR. Our preliminary work showed that clinicians lacking cardiac qualifications may have limited knowledge and awareness of CR and

its benefits.[21] Low agreement among clinicians on patients that are more likely to benefit from CR, clinicians' personal lifestyle and health belief, and the knowledge on the availability and quality of local CR programs also impact on referral to CR.[21] The lack of standard administrative processes of referral and of reliable systems to support clinicians with these processes have also been identified as reasons for limited referrals to CR.[17 21] To address this, the South Australian Department of Health's (SA Health) Integrated Cardiovascular Clinical Network (iCCnet SA), which is a state-wide provider of clinical network support and practice of evidence-based cardiac care and continuous quality improvement servicing regional, rural and remote areas of South Australia, implemented the Country Access to Cardiac Health (CATCH) program.[18 19] This program includes a central referral process that receives CR referrals for patients discharged from public and private hospitals and directs them to a face-to-face or telephone-based CR service depending on patient's preferences and proximity to a CR community centre.[19] In a quasi-experimental pre-post analysis conducted in 2015, regional and rural locations receiving the telephone-based CR program showed an increase in referral rates (97.3%), a reduction in all-cause readmissions (3.4% vs 1.8%, p<0.001), and reduced length of stay for those patients readmitted (3.5 vs 2.7 days, p=0.001) after the program implementation.[19]

*Lack of patient-centred approaches and individualised choices*

The CATCH program also implemented a telephone-based CR service that is offered to patients living at least 50km away from a CR service.[19] The CATCH telephone program is aligned with findings from a systematic review conducted by members of our team that showed that individualised telehealth or home-based CR programs were effective alternative models that are comparable to the traditional hospital and community-based programs in terms of

reducing CVD risk factors.[14 19] These telehealth options are particularly important to Australians living in rural and remote areas where distances and lower availability of services amplify limitations to CR access.[4 17 20 6]

*Lack of sustainable lifelong commitment to CR supported by primary care*

Access to a cardiologist is a known enabler of CR uptake.[22] To address the barrier of the shortage of specialists in rural and remote areas throughout Australia,[23] iCCnet has developed a model of care (GP Hybrid network) that enables CR delivery through a strong collaboration among general practitioners (GPs), practice nurses working in rural and remote areas in South Australia and CR nurses working in the CATCH telephone-based service.[24] This service has been evaluated and shown high attendance and completion rates, and enhanced clinical outcomes for patients within 12 months, such as improved lipids and diabetes control. [24] All these measures of performance of the GP Hybrid network were enabled by the establishment of the CATCH database by iCCnet. This CR dataset with standardised electronic data collection serves to audit and feedback purposes to all public face-to-face services and the telephone-based service in the state of South Australia.[18 25]

*Heterogeneous CR quality*

Quality improvement of CR programs is associated with higher rates of attendance and completion.[25] The Australian Cardiovascular Health and Rehabilitation Association (ACRA) recommends five core components for quality delivery and outcomes of CR services - access to services, assessment and monitoring, recovery and longer-term maintenance, lifestyle or behavioural changes, medication adherence, evaluation and quality improvement.[9] National Quality indicators for CR were established by ACRA and the National Heart Foundation of Australia in 2019.[9] However, currently, there is no standardisation of the CR services and

programs with only a few meeting minimum duration standards.[26] Therefore, there is large variation across services in terms of the content, measures, the number of sessions and length of the CR program.

*Aims and Objectives*

The CHAP project aims to develop and implement evidence-based approaches to address modifiable barriers to accessing and successfully completing CR in rural and remote areas of South Australia.

We hypothesise ($H_1$) that compared with patients not exposed to the CHAP model of care (i.e., receiving standard care) patients exposed to CHAP will have higher rates of attendance and completion of CR; higher rates of risk factor modification; higher rates of adherence to evidence-based pharmacotherapy; experience lower rates of morbidity and mortality at 30 days and 12 months and that the model will demonstrate cost effectiveness for both services and patients.

Specific objectives of the CHAP project are to:

1) Adopt a patient-centred approach by co-designing the CHAP model of care with patients family and clinicians and evaluate the impact on CR attendance and completion

2) Evaluate the clinical effectiveness of the CHAP model and

3) Evaluate the cost-effectiveness of the CHAP model

## METHODS AND ANALYSIS

### Research Design

The CHAP project is implementing a model of care within the real world. To understand and observe the various implementation activities and evaluate their different effects within this

complex context of non-linear and changing processes and elements, we will apply multiple research methods.[27]

The Model for Large Scale Knowledge Translation, which is particularly useful for large scale collaborative projects involving researchers and clinical staff, is a generalisable translation model that will be used to facilitate implementation of evidence-based interventions into practice[28]. The first three of the four stages of the Model for Large Scale Knowledge Translation (1. Summarise the evidence; 2. Identify local barriers, and 3. Measure performance) have been completed in the decade (2009-2018) of preliminary work by researchers in our team and included 1) systematic review on the effectivenesss of alternative modes of delivery of CR;[14] 2) idenification of local barriers to CR attendance;[17] 3) the establishment of a central referral system (CATCH central referral system) and telephone-based program (CATCH telephone program);[18] [19] and 4) clinical database (CATCH database).[18]

The fourth stage of the model is the final and most complex one – *Ensure all patients receive the intervention*. The model uses a "four Es" approach to improve reliability: engage, educate, execute, and evaluate [28] (Figure 1). This is the stage that will be developed in the CHAP project. The CHAP model of care must consider the context, local culture and resources of each hospital and health networks in the current system.

To complete this stage, the team will work closely with health networks and CR services addressing barriers to implementing the CHAP model of care in rural and remote areas of the state (Figure 2).

The evaluation of the CHAP model of care will comprise both clinical (Objective 2) and cost-effectiveness (Objective 3) assessments, and will involve a multi-method approach:

I. A prospective cohort study comparing attendance and clinical outcomes of patients exposed and non-exposed to CHAP - the cohort of patients eligible to CR will be

followed-up for 12 months from CHAP implementation and outcomes will be compared between those exposed to the CHAP model and those not exposed to the model of care. Attendance will be defined as attendance to ≥1 CR program session. Completion was defined as attendance to at least 75% of the CR sessions.[29] The exposed and non-exposed groups will be age, sex and diagnostic-related groups (DRG) matched controls in a 1:3 ratio;[30]

II. A pre-post study design comparing outcomes before (01/01/2016 to 30/06/2021) and after CHAP implementation (01/07/2021 to 30/06/2023). A comprehensive economic analysis will be performed to evaluate the cost efficiencies to health services, and the cost-benefit to rural and remote patients and families.

**Setting**

The CHAP model of care will be implemented within the six local health networks in regional, rural and remote South Australia through iCCnet.[18] The iCCNet is part of the Rural Support Service (RSS) which is a business unit within the South Australian Health Service that provides flexible, responsive and innovative services to support the six regional local health networks. Regional health services are delivered to a population of 497, 003 people with the following age-group distribution: 0 to 4 years - 5.82%, 5 to 18 years -17.52%, 19 to 64 years - 56.68%, and 65 years and over - 19.98%. There are 23 CR services and the CATCH telephone service. [31]

**Participants**

Eligible participants will be defined according to current international guideline criteria [32] by DRGs based on the International Classifications of Diseases-10 (ICD-10) codes and the current guidelines for those who are eligible for referral to CR these include: acute myocardial infarction (I21, I21.0, I21.1, I21.2, I21.3, I21.4, I21.9), hypertensive heart disease (I11.0, I11.9, I13, I13.0, I13.2, I13.9), ischemic heart disease (I20-I25), arrhythmias (I48, I48.0, I48.1, I48.2,

I48.3, I48.4, I48.9, I49.9), and/or heart failure (I50, I50.0, I50.1, I50.9).[33] Eligibility will also be defined based on DRG procedure codes for coronary artery surgery, percutaneous coronary intervention, and ventricular assist device.[34]

All adult (≥18 years) South Australians, including Aboriginal and Torres Strait Islander peoples, discharged from hospital with a diagnosis that meets the eligibility criteria to CR (acute myocardial infarction, hypertensive heart disease, ischemic heart disease, arrhythmias, and/or heart failure, coronary artery surgery, percutaneous coronary intervention, and ventricular assist device) [33] and living within the six local health networks in regional, rural and remote areas will be exposed to the CHAP model of care. The comparison group (non-exposed to CHAP) will be comprised by age, sex and DRG matched controls not living in these regional, rural and remote areas.

With approximately 60% of the Aboriginal and Torres Strait Islander populations of South Australia living in outside major cities in regional and remote areas,[35] it is likely that a number of these individuals will be exposed to the CHAP model of care. However, we acknowledge we are implementing standard guidelines that may not suit these groups. A future project to culturally adapt the CHAP model of care using appropriate Aboriginal and Torres Strait Islander translation methodology is warranted. There will be no stratification by Aboriginal/indigenous status in this study.

**Exposure- The CHAP model of care**

Exposure to the CHAP model of care will be defined as an individual, professional or service receiving at least one of the approaches proposed to address four different local barriers to CR attendance and completion that were previously identified by this team (Figure 2):

*1) Limited number of referrals*

We will address the limited number of referrals by promoting CR endorsement among clinicians and providing them with an electronic system that facilitates referrals.

To increase CR endorsement, we will co-design education resources with clinicians including evidence-based pharmacotherapy resources, and a variety of paper-based, videos and web-based education resources. One example of this is the "Recommend video wall" which was produced by the CHAP project through collection of testimonies from patients who undertook CR and multidisciplinary teams working in hospitals and CR services who recommend CR[36]. This video wall has been displayed in events with professionals and patients and websites of organisations such as ACRA and Heart Foundation as a tool to promote endorsement to CR. This will ensure that health professionals' and CR patients' needs are addressed regardless of technology literacy levels.[37]

We will expand the capabilities of referral introduced by the CATCH central referral system by developing an automatic electronic referral system that will streamline in-hospital referrals. A central portal for patient discharge reports will provide contact information on patients that have been discharged with applicable codes. Currently, these reports are run from several different databases and have the potential to miss patients living in rural and remote areas. We will first have automatic reports generated from information taken from the health department (SAH DataMart™). This will all run on the back end of the Integrated Point of Care Clinical System (iPOCCS™)[38] in which an excel document is generated daily, reporting on the previous 24h of discharged patients. A Uniform Resource Locator (URL) will be sent to designated users allowing them log on to iPOCCS and download the file.

*2) Lack of patient-centred approaches and individualised choices*

Face-to-face and telephone services are well established as modes of CR delivery in rural South Australian regions.[19] Despite variability in duration and content, these CR programs are

generally based on the National Heart Foundation of Australia [32] and ACRA guidelines [9] being comprised of 10 modules (Initial Assessment and Goal Setting, Heart Education and Self-management, Exercise Training and Physical Activity, Healthy Eating and Weight management, Tobacco Cessation and Alcohol Reduction, Medication Education and Review, Managing Medical Risk Factors, Psychosocial Wellbeing, Activities of Daily Living, Reassessment and Completion) which are delivered over 6 to 12 weeks depending on patient's needs and decisions from services.

To expand choices of CR modes of delivery, CHAP will co-design with patients living in rural areas a web-based program accessed through a personal log-in. The *User Experience* (UX) *Design*,[39] an established co-design framework, will guide the engagement with end-users through workshops and the co-design process from concept design to completion. A variety of UX Design methods will be used interchangeably to plan, execute and evaluate the workshops. These include cultural probes, heuristic evaluation, brainstorming, focus groups and concept testing.[39 40] The content of the portal will be based on the 10 National Heart Foundation of Australia modules.[9 32] Individualised programs will be tailored according to patients' needs. The anticipated duration of each web module completion is 30 minutes per week.[40] Those in the web-delivery mode will be required to read short texts, watch short videos (about 5 per module), set personal goals, self-report their dietary, physical activity, smoking and alcohol ingestion habits weekly through responding online questionnaires on the website. The web portal will have a function to collect physical activity data from wearables and smartphone apps patients may use. Patients will be able to interact with a CR nurse through a message system embedded in the web portal. They will be asked to complete four Heart Health Risk Factor Assessments (baseline, 8-12 weeks after starting CR, 6 and 12-months after completing CR). These assessments will comprise clinical and PROMS assessment using validated questionnaires that assess lifestyle habits, exercise capacity, quality of life, mental health

(Table 1). Six and 12-month follow-up will be performed by the patient's primary carer physician.

**Table 1: Primary and Secondary outcomes, measurements and sources of data**

| **Primary outcomes** | **Measures/ Instruments** |
|---|---|
| Attendance/ Completion | Number of patients attending ≥1 session or completing 75% of all sessions among the ones eligible ones/year |
| **Secondary Outcomes** | |
| CR Referral rates | Number of patients referred to CR/eligible to CR/year |
| 30-day and 12-month hospital CVD-related hospital re-admission | Assessed through the linkage between the South Australian CR database and SA Health administrative databases. Each cardiac admission will be counted as a single separation, with admissions involving transfer(s) merged as one. Readmission within 24 hours will not be counted as a new event. |
| 30-day and 12-month CVD-related mortality | Assessed through the linkage between the South Australian CR database and SA Health administrative databases. CVD |
| 30-day and 12-month Emergency Department (ED) presentation | Assessed through the linkage between the South Australian CR database and SA Health administrative databases. Each ED presentation resulting in a separation will be considered a single hospitalisation. New ED presentation within 24 hours will not be counted as a new event. |
| ***Cardiovascular risk factor modification*** | |
| Smoking | Self-reported number of cigarettes |
| Alcohol intake | Self-reported grams of alcohol consumed/week |
| Body mass index | Self-reported weight and height |
| Nutrition | CSIRO Healthy Diet Score[41] |
| Diabetes control | Hb A1C |
| Exercise, physical activity and functional capacity | 6-minute walk test[42] International Physical Activity Questionnaire-Short Form[43] |

| | |
|---|---|
| | Specific Activity Questionnaire[44] |
| Medication adherence | Adherence in Chronic Diseases Scale[45] |
| ***Patient-reported outcome measures (PROMs) and patient-reported experience measures (PREMs)*** | |
| Anxiety | Cardiac anxiety questionnaire [46] |
| Depression | PHQ-2, PHQ-9 [47] |
| Quality of life* | EQ-5D-5L[48]<br>Kansas City Cardiomyopathy Questionnaire-12[49] (for patients with heart failure) |
| Health literacy | Brief Health Literacy Screening tool [50] |
| Patient satisfaction | Self-reported satisfaction |

PHQ-2 and PHQ-9: the 2- and 9-question Patient Health Questionnaires, respectively; EQ-5D-5L: European Quality of Life- 5 Dimensions – 5 Levels;

*Patients and public involvement*

The CHAP model of care is underpinned by a patient-centred approach. Patient-centred care or person-centred care is based on principles that those receiving healthcare must be treated with dignity and respect and be involved in all decisions about their health.[51] This approach is applied in this study through involvement of patients in the co-design of the CR web program[40] and development of a model that allows patients to choose among different CR modes of delivery (face-to-face, telephone or web-based, or combinations of these modes- Figure 2).[19 51 52] We will particularly promote the participation of older CR patients and people from cultural and linguistically diverse backgrounds to ensure that groups at increased risk of low technology and health literacy are involved in the co-designing of the web-based CR program. We anticipate this will increase patient adherence and engagement with the web-based CR program.[52]

Updating the modalities of telehealth that are currently available will allow for greater flexibility of CR delivery which can improve access for patients in need. Importantly, this also

provides an appropriate response to the COVID-19 pandemic when traditional CR service delivery is disrupted. [15 53 54]

*3) Lack of sustainable lifelong commitment to CR supported by primary care*

CHAP project will build upon the GP Hybrid Model of CR delivery by creating a business model which allows primary care to support CR delivery and assessment of CR results (risk factor change) of patients undertaking telephone and web-based CR. The model will comprise a 'Heart Health Risk Factor' pre-assessment at the beginning of the program (i.e. 1-2 weeks post-discharge) which will last 75 minutes (60 minutes with a Practice Nurse and 15 minutes with the GP). Re-assessments will occur at 8-12 weeks after the beginning of the program, and 6 months and 12 months post-completion of the CR program. These will comprise 45 to 60 minutes consultations with the practice nurse, and 15-minute consultations with the GP. This has potential to enable long term support for heart health from GPs.

*4) Heterogeneous CR quality*

The CHAP project will seek adherence to the quality indicators through multiple online and offline professional development programs targeting the practitioners, development of an accreditation program and refinement of data collection tools on the national CR quality indicators. In particular, the project will try to integrate objective patient-generated physical activity tracking data to the CATCH CR database to enable objective monitoring of physical activity during CR and personalised feedback.

**Outcomes**

*Primary outcome* – CR attendance rate defined as the number of patients commencing CR (≥ 1 session) among those eligible to CR.

*Secondary outcomes* - will compare risk factor modification, clinical outcomes, PROMS and PREMS of the CHAP and non-CHAP groups**.** Measurements, tools and questionnaires and data

sources for the secondary outcomes are presented in Table 1. The selection of validated tools and questionnaires followed extensive consultations with CR clinicians about their preferences and implications of the tools to documentation time and costs to the services.

**Data Sources**

The South Australian CR clinical database (the CATCH database) collects data uniformly across metropolitan, rural and remote areas using a standardised electronic entry process, including electronic data capture, of patients moving through public CR services from rural and remote to a metropolitan hospital or vice versa.[19] This database will be linked to the SA Health administrative database, enabling follow-up and assessment of hospital re-admissions, Emergency Department (ED) presentations and mortality.[55] This data linkage approach is similar to the one used to audit the CR services in South Australia from 2013-2015.[12]

**Bias**

To avoid information bias (i.e., systematic differences in the completeness or the accuracy of data leading to differential misclassification of individuals regarding exposures or outcomes) we are up-skilling clinicians to input data onto the CR databases as part of continuous quality improvement processes. The goal is to fill the gap of scarcity of data on CR data in Australia [56] and achieve universal, uniform data entry in South Australian CR programs.

**Sample size**

The average state-wide attendance of CR from 2013-2015 was 28.3% (pre-CHAP estimate)[10]. Based upon a 4% improvement in attendance (i.e., to 32.3%) as reported by the British Association for Cardiovascular Prevention and Rehabilitation audit,[57] a total sample size of 1223 (CHAP) and 3669 (usual care, 1:3 matching) will produce a two-sided 95% confidence interval for the difference in population proportions with a width that is equal to 0.06. Allowing

for a 20% dropout, we will need to observe 1529 patients (765 per year) in the group exposed to CHAP that will be matched to 4587 patients in the group non-exposed to CHAP (usual care) from the CATCH database. From 2015-2019, approximately 2000 patients were entered into the CATCH CR database per year making this study highly feasible.

**Data analysis**

*To evaluate the effectiveness of CHAP (Objective 2)*

Unpaired *t*-tests, χ tests and Mann–Whitney *U* tests for non-normal data will be used for comparisons for the pre-post analysis of the CHAP model components. Statistical significance will be inferred if 2-tailed tests estimated $P<0.05$. Rates of referral, attendance, and completion of CR per year; modification of risk factors; adherence to evidence-based pharmacotherapy morbidity and mortality at 30 days and 12 months will be compared between CHAP and non-CHAP attendees and presented as Odds Ratios and 95% Confidence Intervals. Matching will be conducted by grouping all cases and controls into relevant groupings of Age, Sex and DRG and analysed using the Mantel-Haenszel methods.[58]

Cox regression models adjusted for clinical and social factors (age, sex, the Index of Relative Socio-Economic Advantage and Disadvantage (IRSAD) from the Australian Bureau of Statistics' Socio-Economic Indexes for Areas-SEIFA score,[59] accessibility and Remoteness Index of Australia (ARIA+),[60] primary cardiac diagnosis, Charlson Index,[61] in-hospital length of stay, prior heart failure, coronary disease, atrial fibrillation, revascularisation, malignancy) will be performed to understand the association between exposure to the CHAP model and attendance. For clinical outcomes (30-day and 12-month hospital CVD-related hospital re-admission, 30-day and 12-month CVD-related mortality), the model will also be adjusted for CR attendance.

*To evaluate the cost-effectiveness of CHAP (Objective 3)*

The economic evaluation of the CHAP model including the business model (explore the item numbers that can be utilised to cover GP based CR and items that can be used to employ and train practice nurses to assist with assessment, monitoring, collection of outcomes data and triage to maximise GP consultation time) that involves primary care in CR delivery will comprise: i) the cost efficiencies to health services, and ii) cost-benefit to rural and remote patients and families.

*i. The cost efficiencies to the health services*

All CVD hospitalisations during the follow-up period will be included and assigned a cost, based on the diagnosis-related group category reference and length of stay. Costs of providing CR will be taken from a health system perspective and calculated over 1 year; this includes staffing, consumables, overheads, and capital expenses. Quality-of-life measures will be estimated at baseline, 6 and 12 months after CR completion, using the standard EQ-5D-5L.[48] The utility is defined by the Department of Health and Ageing as a numerical value assigned by an individual to a preference for, or desirability of, a specific level of health status or a specific health outcome. Data on utilities and survival can be combined to calculate Quality-Adjusted Life-Year (QALY) by exposed and non-exposed groups using the Quality-Adjusted Survival Analysis (QASA) method.[62-64] Incremental cost per QALY saved will be calculated as an incremental (rehabilitation v usual care) cost per patient divided by the incremental QALY per patient.[65]

*ii. Cost-benefit to rural and remote patients and families*

Using an economic survey developed by the Western Australian Department of Health[66] we will quantify the economic impact of the CHAP model based on information at baseline including patient demographics such as household structure, employment status and the

distances travelled to access services; the nature of the consultation, waiting time, whether the patient required time off work (and if so, how much), and the mode of transport used to travel to the hospital. The survey will include accompanying persons, and if the person required any time off work to do so. Finally, the survey will explore the patient's treatment options; for example, did they consider having an appointment in the city essential to their care? This data will be modelled to compare two scenarios for face-to-face CR; 1) if the patient travelled to the city to attend CR, or 2) if the patient travelled to the nearest rural CR program if this is within 60 minutes' drive (approximately 100 km). All results will be presented unadjusted for multiple comparisons and all analyses will be done on an intention-to-treat basis. 95% confidence intervals for the difference in QALYs will be calculated with bootstrapping.[63]

**Time Frame of the Project**

The original timeframe comprised a three-year project from 1st July, 2019 to 30th June, 2022. Due to the impact of the COVID pandemic on the project implementation, the project had a 12-month extension and will now be complete by 30th June 2023. Year 1-2 will include project staff employment and training, development of resources, education materials, study protocols, additional datasets, and Ethics approval. Recruitment will be conducted over years 2-3 and follow-up over years 3-4.

## ETHICS AND DISSEMINATION

### Ethics approval and consent to participate

This study was approved by the Southern Adelaide Clinical Human Research Ethics Committee Research Committee on 28th, April 2020 (HREC/20/SAC/78). The data linkage between the South Australian CR clinical database and the Department of Health

administrative databases was approved by the Department for Health and Wellbeing on 26th August, 2021 (2021/HRE00270). All consecutive patients who are eligible for CR according to the recommended DRG codes and referred for CR will have consent waiver to have their data used for this research.

**Dissemination**

Findings will be disseminated to patients and health professionals using various means and media. A public website (https://chapproject.com.au), [36] online educational sessions with patients and health professionals working in CR, monthly newsletters sent to participants via email, social media (Twitter @CHAPproject, LinkedIn CHAP Project and Facebook), and scientific publications and conference presentations.

De-identified data will be available upon reasonable request.

**Authors contributions:** The study was conceived and designed by RC, SN, AB, DC, JB, AM, CM, VV, JH, PT, BK, CZ, IP, RT, RT, and WK. The first draft of the paper was written by AB with significant input from RC before receiving input from remaining authors; CA, KG, KN, HD, SC, MAPP, IL, VP, MR, KW, HM, AK, LG, ML and CG. All authors read and approved the final manuscript.

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## Legend of Figures and Tables

### Figures

Figure 1: Using the Model for Large Scale Knowledge Translation to develop CHAP

Figure 2: Addressing the barriers through the CHAP model of care (Exposure) according to the 4th Stage of the Model for Large Scale Knowledge Translation ('Engage, Educate, Execute, Evaluate')

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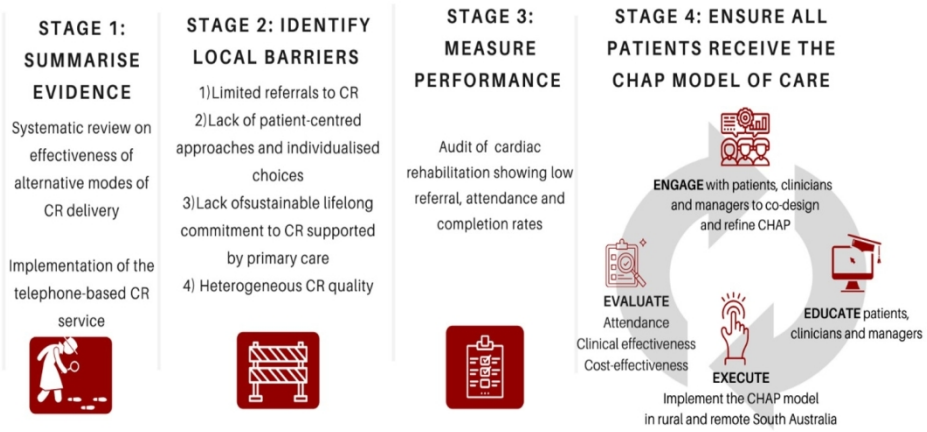


Figure 1: Using the Model for Large Scale Knowledge Translation to develop CHAP

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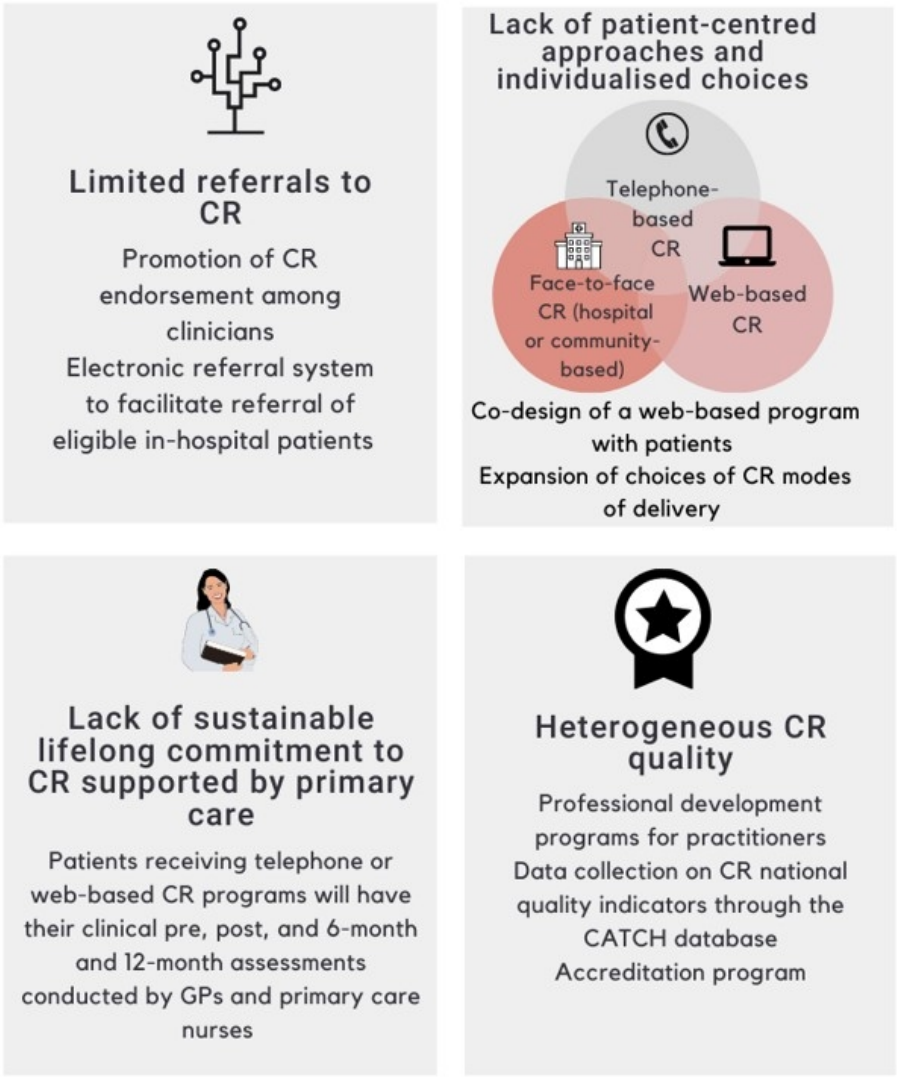


Figure 2: Addressing the barriers through the CHAP model of care (Exposure) according to the 4th Stage of the Model for Large Scale Knowledge Translation ('Engage, Educate, Execute, Evaluate')

174x191mm (96 x 96 DPI)

STROBE CHECKLIST

STROBE Statement—Checklist of items that should be included in reports of ***cohort studies***

| | Item No | Recommendation | Page No |
|---|---|---|---|
| **Title and abstract** | 1 | (*a*) Indicate the study's design with a commonly used term in the title or the abstract<br><br>(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found | 1<br><br>4 |
| **Introduction** | | | |
| Background/rationale | 2 | Explain the scientific background and rationale for the investigation being reported | 8-10 |
| Objectives | 3 | State specific objectives, including any prespecified hypotheses | 11 |
| **Methods** | | | |
| Study design | 4 | Present key elements of study design early in the paper | 12 |
| Setting | 5 | Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection | 13 |
| Participants | 6 | (*a*) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up<br><br>(*b*) For matched studies, give matching criteria and number of exposed and unexposed | 14 |
| Variables | 7 | Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable | 14-18 |
| Data sources/ measurement | 8* | For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group | 18 |
| Bias | 9 | Describe any efforts to address potential sources of bias | 19 |
| Study size | 10 | Explain how the study size was arrived at | 19 |

| | | | | |
|---|---|---|---|---|
| | Quantitative variables | 11 | Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why | 20-21<br>Table 1 |
| | Statistical methods | 12 | (*a*) Describe all statistical methods, including those used to control for confounding<br>(*b*) Describe any methods used to examine subgroups and interactions<br>(*c*) Explain how missing data were addressed<br>(*d*) If applicable, explain how loss to follow-up was addressed<br>(*e*) Describe any sensitivity analyses | 20-21 |
| **Results -Not applicable** | | | | |
| Participants | | 13* | (a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed | |
| | | | (b) Give reasons for non-participation at each stage | |
| | | | (c) Consider use of a flow diagram | |
| Descriptive data | | 14* | (a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders | |
| | | | (b) Indicate number of participants with missing data for each variable of interest | |
| | | | (c) *Cohort study*—Summarise follow-up time (eg, average and total amount) | |
| Outcome data | | 15* | *Cohort study*—Report numbers of outcome events or summary measures over time | |
| | | | *Case-control study*—Report numbers in each exposure category, or summary measures of exposure | |
| | | | *Cross-sectional study*—Report numbers of outcome events or summary measures | |
| Main results | | 16 | (*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included | |
| | | | (*b*) Report category boundaries when continuous variables were categorized | |
| | | | (*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period | |

| | | |
|---|---|---|
| Other analyses | 17 | Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses |
| **Discussion** | **Not applicable** | |
| Key results | 18 | Summarise key results with reference to study objectives |
| Limitations | 19 | Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias |
| Interpretation | 20 | Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence |
| Generalisability | 21 | Discuss the generalisability (external validity) of the study results |
| **Other information** | | |
| Funding | 22 | Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based **Page 23** |